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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,603	01/09/2002	Nicholas Thomas	PA-9902	7928

22840 7590 09/15/2003

AMERSHAM BIOSCIENCES
PATENT DEPARTMENT
800 CENTENNIAL AVENUE
PISCATAWAY, NJ 08855

EXAMINER

CHAKRABARTI, ARUN K

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/914,603

Applicant(s)
Thomas

Examiner
Arun Chakrabarti

Art Unit
1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 18, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☒ Other: *Detailed Action*

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DETAILED ACTION

Specification

1. Claim 1 has been amended. Claims 1-17 are currently pending in this application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Kamb et al. (PCT International Application Number WO 98/26098) (June 18, 1998).

Kamb et al. teaches a method of detecting and analyzing differences between nucleic acids from two sources (Abstract), which method comprises:

- a. providing the nucleic acids from two sources as labeled probes wherein the nucleic acids from two sources are labeled with two different markers (Abstract, Claim 1, Figure 1, and Examples 1, 2, and 12);
- b. forming a mixture of the labeled probes with pooled reagents wherein each of the pooled reagents comprises a population of beads carrying a polynucleotide target, the

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polynucleotide target of any one of the pooled reagents being different from the target of any other of the pooled reagents and the beads of any one of the pooled reagents being distinguishable from the beads of any other of the pooled reagents (Abstract, Claim 1, Figure 1, and Examples 1, 2, and 12);

c. incubating the mixture under conditions to promote specific hybridization between probes and targets (Abstract, Claims 1-2, Figures 1, 15B, and Examples 1, 2, and 12); and

d. analyzing each bead in the mixture by flow cytometry (Example 2 and page 33, lines 16-23 and Figures 17-18 and Example 18, Page 87, line 17 to page 88, line 19).

Kamb et al. teaches a method, wherein the nucleic acids from the two sources are mRNA or cDNA from cells or tissues (Figures 8, 14, 18A-D).

Kamb et al. teaches a method, wherein the polynucleotide targets are cDNA derived from cellular mRNA (Page 57, lines 3-5 and Examples 9 and 12).

Kamb et al. teaches a method, wherein the polynucleotide targets are PCR amplimers (Example 9).

Kamb et al. teaches a method, wherein the polynucleotide targets contain terminal biotin groups through which they are attached to streptavidin-coated beads (Page 34. Lines 3-8).

Kamb et al. teaches a method, wherein the polynucleotide targets and the nucleic acids are single-stranded nucleic acids (Figures 1, 11, 13, 14, and 18).

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Kamb et al. teaches a method, wherein beads of one pooled reagents are distinguishable from beads of another pooled reagents by size, nature, or concentration of one or more markers attached to the beads (Examples 17-19 and claim 2-13, 25-33).

Kamb et al. teaches a method, wherein fluorescent markers are attached to beads (Page 68, lines 12-16 and Figure 11).

Kamb et al. teaches a method, wherein each of the nucleic acids is labeled with a fluorescent tag to indicate its source (Figures 1, and 11 and Page 30, line 4 to page 33, line 11).

Kamb et al. teaches a method further comprising the step of analyzing the data obtained by flow cytometry to yield information about the relative and/or absolute abundance of individual nucleic acid sequences contained within the nucleic acids from two sources (Example 2 and page 33, lines 16-23 and Figures 17-18 and Example 18, Page 87, line 17 to page 88, line 19).

Response to Amendment

4. In response to amendment, objection to claim 1 has been withdrawn. However, 102(b) rejection has been maintained properly.

Response to Arguments

5. Applicant's arguments filed on July 18, 2003 have been fully considered but they are not persuasive.

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In response to applicant's argument (page 5, last paragraph to page 6, line 3) that the Kamb references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., (I) each bead of a detectable type carries the same known nucleic acid sequence and (ii) subsequent analysis of the beads in the mixture by flow cytometry, allows direct quantification of the relative abundance of any specific, known target) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues (page 6, lines 4-11) that rejection based on Kamb reference should be withdrawn because beads used by Kamb carries one unique sequence and are not distinguishable from beads carrying a different unique sequence by flow cytometry and the identity of the sequence can not be determined during flow sorting and therefore an additional step has to be taken to determine "the identity of the nucleic acid molecules" of interest. Applicant's argument is not persuasive for two reasons. (1) The novelty of the invention of step to determine "the identity of the nucleic acid molecules" of interest is missing from claim 1(d). (2) In presence of open "comprising" language of the claim any additional step(s) or material(s) can be included in the method steps of the claimed invention and Kamb clearly teaches how to identify and recover specific sequences in a complex population of target nucleic acids and explicitly teaches that each nucleic acid sequence of cDNA library "possess its own unique identifier tag" (Page 30, lines 8-12).

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In view of the response to argument, 102 (a) rejection is hereby properly maintained.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979. Any inquiry of a general nature or relating to the status of this application or

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proceeding should be directed to the Group LIE Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

September 11, 2003


GARY BENZON, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800